IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	**Confirmation No. 2522**
Yasuo FUKAGAWA et al.	:	Docket No. 00325/CH:TKU, PC/E-6-627US
Serial No. 09/284,578	:	Group Art Unit 1617
Filed October 8, 1999	:	Examiner Edward J. Webman
BIOLOGICALLY ACTIVE POLYMER PRODUCTS	:	THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEE FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975.

RESPONSE AFTER FINAL REJECTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE UNDER 37. CFR
EXPEDITED PROCEDURE
EXAMINING GROUP 1617

Sir:

Responsive to the Office Action of June 24, 2003, the time for responding thereto being extended for one month in accordance with a Petition for Extension submitted herewith, Applicants submit the following remarks in support of the patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims. Further and favorable reconsideration is respectfully requested in view of these remarks.

Thus, the rejection of claims 1-7, 11, 24 and 26 under 35 U.S.C. §102(b) as being anticipated by Guire, as well as the rejection of claims 1-6, 11, 24 and 26 under 35 U.S.C. §102(b) as being anticipated by Patnaik et al. '165, the rejection of claims 8-9 under 35 U.S.C. §103(a) as being unpatentable over Guire further in view of notice under MPEP 2144.03, the rejection of claims 6-9 under 35 U.S.C. §103(a) as being unpatentable over Patnaik et al. '165, the rejection of claims 1-6, 11, 30 and 31 under 35 U.S.C. §102(b) as being anticipated by Sugo and the rejection of claims 1-7,

9, 11 and 31 under 35 U.S.C. §102(b) as being anticipated by Goldberg et al., are respectfully traversed.

Each of Guire, Patnaik et al. and Goldberg et al. commonly teaches that sites of a substrate, to which a biologically active or biocompatible agent is bound, exist on the surface of a substrate.

More specifically, Guire discloses the use of a photochemically reactive group capable, upon activation, of covalently bonding to a solid surface. It is clear that Guire discloses the use of a photo-graft reaction which can form radicals only on the surface of the substrate.

Patnaik et al. discloses that a biologically active agent is bound to and coats a hydrophobic surface of a substrate. The biologically active agent comprises a polymer and a biological agent bound to the polymer. Problems which may be caused by such a coating are that the coating is easily peeled off or eluted from the polymer.

Goldberg et al. discloses a method for modifying the surface of a substrate material adapted for contact with tissue of a human or non-human animal such as contact lenses, which method comprises exposing the surface to a solution comprising (a) a neutral or ionic water-soluble hydrophilic vinylic monomer and (2) at least one biofunctional agent, and irradiating the surface with gamma or electron beam irradiation in the presence of the solution, thereby forming on the surface a graft polymerized coating having physically entrapped therein or chemically bonded thereto molecules of the biofunctional agent.

Alternatively, a method is carried out by exposing the surface of the substrate to a solution of a neutral or ionic water-soluble hydrophilic vinylic monomer, and irradiating the surface with gamma or electron beam irradiation in the presence of the solution, thereby forming on the surface a graft polymerized coating, and then soaking the product in a solution of at least one biofunctional agent to diffuse the agent into the polymerized surface.

The grafted chains of Goldberg are bound only on the surface of the substrate and therefore a biologically active agent is attached on the surface of the substrate.

Sugo discloses an antimicrobial material which is produced by graft polymerizing a reactive monomer on a base material and introducing a functional group having a function of removing harmful ions combined with an antimicrobial activity into the grafted chain of the graft polymer. The

graft polymer having those functional groups exhibits an anti-fungal or anti-bacterial activity, which is not a selective biological activity. That is, the graft polymer of Sugo is a non-selective polymeric anti-fungal compound which differs from that of the present invention.

The product of the present invention

As defined in the claims, the present invention relates to a biologically active polymer product which is prepared by chemically binding a biologically active compound to a substrate through a graft chain by means of irradiation graft polymerization. The polymer prepared according to the present invention exhibits selective biologically activity because the biologically active compound has selective activity.

The amount of the graft chains which are introduced in the polymer molecules by means of irradiation graft polymerization is sufficient to provide sufficient numbers of functional groups such as carboxyl groups to which an active compound is to be bound.

According to Example 1 of the present application, the acrylic acid graft rate was 78.5 % (page 42, lines 3-4). That is, about 80% of graft chains are introduced in a substrate polymer, which graft chains provide sufficient numbers of carboxyl groups. In addition, the acrylic acid graft chains usually have a molecular weight of about several hundred thousands and have a considerable length. Thus, these graft chains provide sufficient capacity to bind the active compounds.

Incidentally, although Sugo discloses that a functional group is introduced to a substrate polymer, the functional group has a relatively low molecular weight and therefore it is easy to bind any moiety of the polymer molecule. Sugo does not disclose the introduction of a functional group having a relatively high molecular weight. In addition, the introduced functional group is not selective and is non-selective to a target substance such as fungi or bacteria.

With particular regard to claim 31, which is directed to a method for producing a biologically active polymer product, in rejecting this claim the Examiner relies on Sugo and Goldberg et al. In connection with the rejection based on Sugo, the Examiner states that the process of making a graft chain with a pendant active moiety is not a patentable limitation in a composition claim. Similarly, in connection with the rejection of claim 31 based on Goldberg et al., the Examiner states that as to

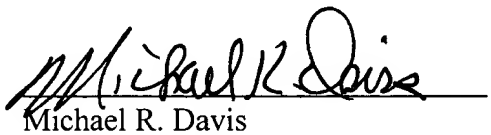
the claimed process, process steps are not considered patentable during prosecution of product-by-process claims before the PTO. However, these arguments are not applicable to claim 31, which is neither a product claim nor a product-by-process claim. In the case of claim 31, the process steps must be considered in determining patentability.

For the reasons set forth above, Applicants take the position that the presently claimed invention is patentable over the applied references.

Therefore, in view of the foregoing remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

Yasuo FUKAGAWA et al.

By: 

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